### Accrual to NCI Approved Treatment Trials Conducted by Your Research Base available for Use by CCOPs 1, 2

Column (1) Provide the Title of the Treatment Trial **Directions:** 

Column (3) Indicate pharmacologic phase as Phase I, II, III or Adjuvant.

Column (6) Indicate projected completion date based on current accrual rate, if applicable.

(1)	(2)	(3)	(4)	(5)	(6)	(7)		
Title	NCI Protocol	Pharmacologic Phase	Disease Site	Date Opened	Projected Completion	Number of Pa Enter	tients/Credits ed <sup>1,2, 3</sup>	
	Number				Date	7/1/08 thru 6/30/09 patients/credit	Total Since Opened patients/credits	
						1	1	
						1	1	
						1	1	
						1	1	
						1	1	
						1	1	

	Total:	1	1

<sup>&</sup>lt;sup>1</sup>Renewal applicants should only count patients/credits entered through the CCOPS, not through Members/Affiliates.
<sup>2</sup>New applicants may report members= activity, since CCOPS were not available.

<sup>&</sup>lt;sup>3</sup> For information on <u>credits</u> see <u>http://prevention.cancer.gov/programs-resources/programs/ccop/credit</u>

Accrual to NCI Approved Cancer Prevention and Control Trials conducted by your Research Base for Use by CCOPS, Members/Affiliates, and other Research Base Members/Affiliates (if for Intergroup Studies)<sup>1,2.</sup>
(List only trials approved by the DCP Cancer Prevention and Control Protocol Review Committee<sup>3</sup>. In Column (5) indicate projected completion date based on current

accrual rate, if applicable.

(1)	(2) NCI	(3) Target	(4) Date	(5) Projected	(6) Credit <sup>6</sup>	(7) Number of Subjects/Credits Entered						
(Precede with an * if Inter-group Trial)	Protocol Number	Sample Size	Opened	Completion Date	Per Entry	CCOP⁴		Member/	/Affiliate	Intergroup Studies <sup>1, 2</sup> Other RB Member/Affil		
									thru Since thru S	Total* Since Opened	7/1/08 thru 6/30/09	Total* Since Opened
						(a) subjects/ credits <sup>6</sup>	(b) subjects	(c) subjects /credits <sup>6</sup>	(d) subjects	(e) subjects /credits <sup>6</sup>	(f) subjects	
						1		1		I		
						1		1		I		
						1		1		I		
						I		1		I		
				Column Total fo	or Table 2a	Subj/Credits	Subjects	Subj/Credit	s Subjects	Subj/Credits	Subjects	

Grand Total Credits 7/1/07-6/30/08: \_\_\_\_\_ [Add credits in columns 7(a), 7(c), and 7(e)]. <sup>1</sup> Only include Inter-group trials where the Research is the Data Coordinating Center.

<sup>&</sup>lt;sup>2</sup> Do not include Inter-group trials from other Research Bases.

<sup>&</sup>lt;sup>3</sup> Other than DCP-approved trials may be listed if new applicant.

<sup>&</sup>lt;sup>4</sup> For DCP approved trials with credit assigned to CCOP only, enter the number of participants and zero (0) credits

<sup>&</sup>lt;sup>5</sup>Provide copies of any abstracts/manuscripts related to the trials listed above.

<sup>&</sup>lt;sup>6</sup> For information on credits see http://prevention.cancer.gov/programs-resources/programs/ccop/credit

Accrual to Inter-group NCI Approved Cancer Prevention and Control Trials sponsored by other CCOP Research Bases for Use by Your Members/Affiliates.

(List only trials approved by the DCP Cancer Prevention and Control Protocol Review Committee.) In Column (5) indicate projected completion date based on current accrual rate, if applicable.

(1) Title <sup>1</sup>	(2) (3)  NCI Target	I Target	NCI Target Date Projected	(2) (3) (4) (5) Numb		Number of St Membe	(6) ubjects Entered r/Affiliate
	Protocol Number	Sample Size	Opened	Completion Date	7/1/08 thru 6/30/09	Total Since Opened	

<sup>&</sup>lt;sup>1</sup> Provide copies of any abstracts/manuscripts related to the trials listed above.

## Cancer Prevention and Control Concepts Approved by NCI for Protocol Development (see <a href="http://prevention.cancer.gov/programs-resources/programs/ccop/credit">http://prevention.cancer.gov/programs-resources/programs/ccop/credit</a>)

(List only concepts approved by the DCP Cancer Prevention and Control Concept Review Committee since June 1, 2008) 1

<u>Directions</u>: In Column (5) indicate projected completion date based on current accrual rate, if applicable.

(1) Concept	(2) NCI	(3) Target Sample Size	Protocol	(5) Projected Duration	(6) Estimated Annual Accrual (Subjects)		
Title	Concept Number	Sample Size	Submission Date	of Study	CCOP	Member/ Affiliate	

Total:

<sup>&</sup>lt;sup>1</sup>New applicants may list trials other than DCP-approved trials.

(1) Concept Title	(2) Target Population	(3)  Projected  Concept  Submission  Date	(4) Projected Duration of Study	(5) Total Sample Size

#### **CCOP Affiliations**

Directions: Please include copies of signed Affiliation Agreements between the Research Base and each CCOP

(1)	(2)		(5) Projected Annual Accrual						
CCOP Name	Full Name of Principal	Trea	atment	Cancer Prevention and Control					
	Investigator	Patients	Credits <sup>1</sup>	Subjects	Credits <sup>1</sup>				
		Т	otal: [TX:	[CC:					

Total:	[TX:	 ][	CC:	

<sup>&</sup>lt;sup>1</sup>For information on <u>credits</u> see <u>http://prevention.cancer.gov/programs-resources/programs/ccop/credit</u>

### Member/Affiliate Participation in NCI Approved Cancer Prevention and Control Clinical Trials

(1)	(2)	(3)		4) nnual Accrual ed at your RB only
Member/Affiliate Name	Full Name of Principal Investigator	Location City, State, Zip	Subjects	Credits <sup>1</sup>

「otal:	 
Olai.	

<sup>&</sup>lt;sup>1</sup>For information on <u>credits</u> see <u>http://prevention.cancer.gov/programs-resources/programs/ccop/credit</u>

#### "Prevention Members"

Please list the cooperative group members, affiliate programs and/or cancer center affiliates other than CCOPs that are included in the application as Prevention Members.

Indicate with a (X) which of the following activities the "Prevention Member" contributes to in a significant way relative to the goals of the Research Base.

- (4) Substantial accrual to chemoprevention studies
- (5) Leadership in study implementation and management
- (6) Scientific leadership in the development of prevention clinical trials
- (7) Active membership in research base cancer prevention committees
- (8) Conduct of preclinical studies and/or Phase I and II clinical trials necessary for drug development
- (9) Conduct of correlative research, such as that related to mechanisms of action, biomarkers, molecular targets, etc.

Include a proposal for each "Prevention Member" that describes how the member will contribute to the goals of the Research Base related to cancer prevention (See RFA Section IV. 2. B. Form and Content of Application for CCOP Research Base Award, Section 5: Membership). A separate budget must be provided for each "Prevention Member.

(1)	(2)	(3)	A	Areas of Significant Contribution						
Member/Affiliate Name	Full Name of Principal Investigator	Location City, State, Zip	(4)	(5)	(6)	(7)	(8)	(9)		

# Reporting On-Site Auditing Activities for Cancer Prevention Trials, Large-scale e.g., (STAR), and Other Trials, if applicable

<u>For Large-scale Prevention Trials</u>, e.g., the Study of Tamoxifen and Raloxifene (STAR), provide a list of ALL the participating institutions along with the audit schedule (MUST be provided) using the Table Format below.

<u>For Other Prevention Trials</u> that include participating Institutions other than Cooperative Group Treatment Trial institutions, provide a list of only these other institutions with their Audit Schedule using the Table Format below.

NCI Institution No.	Name	Parent	Membership Date	Current Status (Active/Terminated)	Accrual ——*	Accrual ———*	Accrual *	Accrual Projected for upcoming year*	Date of last Audit	Date of Next proposed audit

<sup>\*</sup>Fill in accrual blank with year (this should cover the preceding 36 months (e.g., 2006, 2007, 2008), if applicable.